U.S. Application Serial No: 10/692,523

Applicants: Bacopoulos et al.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A method of treating leukemia in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat leukemia in said subject.

- 2. (Original) The method of claim 1, wherein the leukemia is an acute leukemia.
- 3. (Original) The method of claim 2, wherein the leukemia is Acute Myeloid Leukemia (AML).
- 4. (Original) The method of claim 3, wherein the AML is undifferentiated AML, myeloblastic leukemia with minimal maturation, promyelocytic leukemia, myelomonocytic leukemia, myelomonocytic leukemia with eosinophilia, monocytic leukemia, erythroid leukemia, or megakaryoblastic leukemia.
- 5. (Original) The method of claim 2, wherein the leukemia is Acute Lymphocytic Leukemia (ALL).
 - 6. (Original) The method of claim 5, wherein the ALL is a subtype L1, L2 or L3

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(Burkitt's type leukemia) as classified by the French-American-British (FAB) classification.

- 7. (Original) The method of claim 1, wherein the leukemia is a chronic leukemia.
- 8. (Original) The method of claim 7, wherein the leukemia is Chronic Lymphocytic Leukemia (CLL).
- 9. (Original) The method of claim 7, wherein the leukemia is Chronic Myeloid Leukemia (CML).
 - 10. (Original) The method of claim 7, wherein the leukemia is Hairy Cell Leukemia.
 - 11. (Cancelled)
- 12. (Currently amended) The method of claim 11_1, wherein said composition is contained within a gelatin capsule.
- 13. (Original) The method of claim 12, wherein said carrier or diluent is microcrystalline cellulose.
- 14. (Original) The method of claim 13, further comprising sodium croscarmellose as a disintegrating agent.
- 15. (Original) The method of claim 14, further comprising magnesium stearate as a lubricant.
- 16. (Currently amended) The method of claim <u>11_1</u>, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 17. (Original) The method of claim 16, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 18. (Original) The method of claim 16, wherein said composition is administered twice daily at a dose of about 200-400 mg.
 - 19. (Original) The method of claim 16, wherein said composition is administered twice

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daily at a dose of about 200-400 mg intermittently.

20. (Original) The method of claim 19, wherein said composition is administered three to five days per week.

- 21. (Original) The method of claim 19, wherein said composition is administered three days a week.
- 22. (Original) The method of claim 21, wherein said composition is administered at a dose of about 200 mg.
- 23. (Original) The method of claim 21, wherein said composition is administered at a dose of about 300 mg.
- 24. (Original) The method of claim 21, wherein said composition is administered at a dose of about 400 mg.
- 25. (Original) The method of claim 16, wherein said composition is administered three times daily at a dose of about 100-250 mg.
- 26. (Original) The method of claim 25, wherein said composition is administered three times daily at a dose of 150 mg.
- 27. (Currently amended) A method of treating Acute Myeloid Leukemia (AML) in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically

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acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat AML in said subject.

28. (Original) The method of claim 27, wherein the AML is undifferentiated AML, myeloblastic leukemia with minimal maturation, promyelocytic leukemia, myelomonocytic leukemia, myelomonocytic leukemia with eosinophilia, monocytic leukemia, erythroid leukemia, or megakaryoblastic leukemia.

29. (Cancelled)

- 30. (Currently amended) The method of claim 29_27, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 31. (Original) The method of claim 30, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 32. (Original) The method of claim 30, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 33. (Original) The method of claim 30, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 34. (Original) The method of claim 30, wherein said composition is administered three times daily at a dose of about 100-250 mg.
- 35. (Currently amended) A method of treating Acute Lymphocytic Leukemia (ALL) in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically

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acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat ALL in said subject.

36. (Original) The method of claim 35, wherein the ALL is a subtype L1, L2 or L3 (Burkitt's type leukemia) as classified by the French-American-British (FAB) classification.

37. (Cancelled)

- 38. (Currently amended) The method of claim 37_35, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 39. (Original) The method of claim 38, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 40. (Original) The method of claim 38, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 41. (Original) The method of claim 38, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 42. (Original) The method of claim 38, wherein said composition is administered three times daily at a dose of about 100-250 mg.
- 43. (Currently amended) A method of treating Chronic Lymphocytic Leukemia (CLL) in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat CLL in said subject.

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44. (Cancelled)

- 45. (Currently amended) The method of claim 44_43, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 46. (Original) The method of claim 45, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 47. (Original) The method of claim 45, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 48. (Original) The method of claim 45, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 49. (Original) The method of claim 45, wherein said composition is administered three times daily at a dose of about 100-250 mg.
- 50. (Currently amended) A method of treating Chronic Myeloid Leukemia (CML) in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat CML in said subject.

51. (Cancelled)

52. (Currently amended) The method of claim 51_50, wherein said composition is administered once-daily, twice-daily or three times-daily.

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- 53. (Original) The method of claim 52, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 54. (Original) The method of claim 52, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 55. (Original) The method of claim 52, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 56. (Original) The method of claim 52, wherein said composition is administered three times daily at a dose of about 100-250 mg.
- 57. (Currently amended) A method of treating Hairy Cell Leukemia in a subject, said method comprising the step of <u>orally</u> administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the amount administration of SAHA is effective to treat Hairy Cell Leukemia in said subject.

58. (Cancelled)

- 59. (Currently amended) The method of claim 58_57, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 60. (Original) The method of claim 59, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 61. (Original) The method of claim 59, wherein said composition is administered twice daily at a dose of about 200-400 mg.

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- 62. (Original) The method of claim 59, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 63. (Original) The method of claim 59, wherein said composition is administered three times daily at a dose of about 100-250 mg.

64. - 94. (Cancelled)

- 95. (New) The method of claim 17, wherein the composition is continuously administered once daily at a dose of 400 mg.
- 96. (New) The method of claim 19, wherein the composition is administered twice daily at a dose of 100 mg or 200 mg intermittently.
- 97. (New) The method of claim 96, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 98. (New) The method of claim 25, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 99. (New) The method of claim 98, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
- 100. (New) The method of claim 25, wherein the composition is administered three times daily at a dose of 200 mg intermittently.
- 101. (New) The method of claim 100, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 102. (New) The method of claim 18, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 103. (New) The method of claim 31, wherein the composition is continuously administered once daily at a dose of 400 mg.
 - 104. (New) The method of claim 32, wherein the composition is administered twice

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daily at a dose of 100 mg or 200 mg intermittently.

105. (New) The method of claim 104, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.

- 106. (New) The method of claim 34, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 107. (New) The method of claim 106, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
- 108. (New) The method of claim 34, wherein the composition is administered three times daily at a dose of 200 mg intermittently.
- 109. (New) The method of claim 108, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 110. (New) The method of claim 32, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 111. (New) The method of claim 39, wherein the composition is continuously administered once daily at a dose of 400 mg.
- 112. (New) The method of claim 41, wherein the composition is administered twice daily at a dose of 100 mg or 200 mg intermittently.
- 113. (New) The method of claim 112, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 114. (New) The method of claim 42, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 115. (New) The method of claim 114, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
 - 116. (New) The method of claim 42, wherein the composition is administered three

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times daily at a dose of 200 mg intermittently.

117. (New) The method of claim 116, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.

- 118. (New) The method of claim 40, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 119. (New) The method of claim 46, wherein the composition is continuously administered once daily at a dose of 400 mg.
- 120. (New) The method of claim 48, wherein the composition is administered twice daily at a dose of 100 mg or 200 mg intermittently.
- 121. (New) The method of claim 120, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 122. (New) The method of claim 49, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 123. (New) The method of claim 122, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
- 124. (New) The method of claim 49, wherein the composition is administered three times daily at a dose of 200 mg intermittently.
- 125. (New) The method of claim 124, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 126. (New) The method of claim 47, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 127. (New) The method of claim 53, wherein the composition is continuously administered once daily at a dose of 400 mg.
 - 128. (New) The method of claim 55, wherein the composition is administered twice

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daily at a dose of 100 mg or 200 mg intermittently.

129. (New) The method of claim 128, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.

- 130. (New) The method of claim 56, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 131. (New) The method of claim 130, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
- 132. (New) The method of claim 56, wherein the composition is administered three times daily at a dose of 200 mg intermittently.
- 133. (New) The method of claim 132, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 134. (New) The method of claim 54, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 135. (New) The method of claim 60, wherein the composition is continuously administered once daily at a dose of 400 mg.
- 136. (New) The method of claim 62, wherein the composition is administered twice daily at a dose of 100 mg or 200 mg intermittently.
- 137. (New) The method of claim 136, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 138. (New) The method of claim 63, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 139. (New) The method of claim 138, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
 - 140. (New) The method of claim 63, wherein the composition is administered three

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times daily at a dose of 200 mg intermittently.

- 141. (New) The method of claim 140, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 142. (New) The method of claim 61, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 143. (New) A method of treating Myelodysplastic Syndrome (MDS) in a subject, said method comprising the step of orally administering to the subject a total daily dose of up to 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) represented by the structure:

or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein administration of SAHA is effective to treat MDS in said subject.

- 144. (New) The method of claim 143, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 145. (New) The method of claim 144, wherein said composition is administered once daily at a dose of 200-600 mg.
- 146. (New) The method of claim 144, wherein said composition is administered twice daily at a dose of 200-400 mg.
- 147. (New) The method of claim 144, wherein said composition is administered twice daily at a dose of 200-400 mg intermittently.
- 148. (New) The method of claim 144, wherein said composition is administered three times daily at a dose of 100-250 mg.

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149. (New) The method of claim 145, wherein the composition is continuously administered once daily at a dose of 400 mg.

- 150. (New) The method of claim 147, wherein the composition is administered twice daily at a dose of 100 mg or 200 mg intermittently.
- 151. (New) The method of claim 150, wherein the composition is administered twice daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 152. (New) The method of claim 148, wherein the composition is administered three times daily at a dose of 100-250 mg intermittently.
- 153. (New) The method of claim 152, wherein the composition is administered three times daily at a dose of 100-250 mg for 14 days followed by 1 week without dose administration.
- 154. (New) The method of claim 148, wherein the composition is administered three times daily at a dose of 200 mg intermittently.
- 155. (New) The method of claim 154, wherein the composition is administered three times daily at a dose of 200 mg for 14 days followed by 1 week without dose administration.
- 156. (New) The method of claim 146, wherein the composition is administered twice daily at a dose of 300 mg for 3 days per week.
- 157. (New) The method of any one of claims 95, 97, 99, 101-103, 105, 107, 109-111, 113, 115, 117-119, 121, 123, 125-127, 129, 131, 133-135, 137, 139, 141-142, 149, 151, 153, 155 and 156, wherein SAHA is the active ingredient in said composition.